Drug - Research - Development

New Orleans Medical Clinic

Rec'd 11/18/99
16

November 16, 1999

Secretary of Department of Health and Human Services
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20857

Re: Docket No. 98N-0617

Dear Secretary:

As per your request in the proposed rules of the new 42 CFR part 8, I am submitting the following comments regarding the *Unsupervised Use of Methadone* section of the above mentioned draft. The specific purpose of these comments is to oppose Option 2 of the *Unsupervised Use of Methadone.* Option 1 (retain existing system) or Option 4 (retain existing requirements subject to continuous review by accreditation bodies) would be more appropriate choices for the new proposed rules.

While the introductory material accompanying the proposed regulations promotes a number of positive aims and goals, specific provisions of the proposed regulations are inconsistent with achieving those positive ends. In certain cases, these provisions would actually result in negative outcomes which are far worse than the current outcomes resulting from the existing regulatory model. Here it should be noted that the following criticisms are not a condemnation of the accreditation model itself, but merely an attempt to point out areas of the proposed regulations which may be improved to achieve the desired results.

The area of the proposed rules which raises a number of significant concerns for treatment providers is that of the *Unsupervised Use of Methadone.* According to the proposed rules, DHHS believes that the take-home schedule of Option 2 reflects the appropriate patient responsibility time frames and adequately balances the need for clinical judgment with the risk of medication diversion. With due respect to the secretary, this individual treatment provider finds the balance of Option 2 inappropriate and inconsistent with the positive aims of the proposed rules.

The intent of the new regulations is to improve the quality of care through the use of increased medical supervision and the assessment of patient outcomes. An additional goal of proposed regulations is to move methadone treatment within the mainstream of the medical community and decrease the current stigma associated with methadone

98N-0617 C45

530 S. Galvez Street • New Orleans, Louisiana 70119 • (504) 524-7205

treatment. The effect of Option 2, however, contravenes the stated objectives of the proposed regulations.

Option 2 provides for a significant increase in the number of methadone doses placed in the custody of an opiate addicted patient. Under provision 5 in Option 2, a patient would be eligible after only 1 year in treatment for a 3 1 day supply of take-home medication and merely monthly visits.

The proposed codification of the above provision would result in several negative ramifications.

The quality of patient care, in most cases, will suffer by reducing a patient's participation in treatment to 12 visits per year. It is the opinion of this provider that Option 2 minimizes the importance of counseling and other social services as a necessary component of recovery and maintaining sobriety. Remaining stable and free from illicit drug use during a period of time in methadone treatment should not be regarded as having achieved a permanent state of recovery. In fact, regular participation in counseling and other social services should be regarded as essential to preventing relapse. A treatment provider should be influencing and motivating a patient to engage in positive change as directed by a professional treatment plan, not merely acting as a pharmacy after a short period of time.

With patient contact limited to twelve visits per year, narcotic treatment programs can not adequately assess the eight criteria necessary to determine that an individual is responsible to handle such a large quantity of medication. There is clearly not enough patient contact to determine whether or not a patient has used illicit drugs, has sold some his or her medication, engaged in criminal activity, or become unstable during the past month. The treatment provider cannot determine whether the client is capable of regular attendance because the patient need only visit the treatment facility twelve times per year. Furthermore, the ability of the treatment program to assess patient outcomes in this situation has been compromised. Urinalysis testing will become compromised due to the fact that testing is no longer random and the patient can plan his/her behavior to coincide with the dates of his/her monthly testing.

A provision allowing 12 yearly treatment visits also ignores the possibility of the patient moving from methadone maintenance to drug-free abstinence. Methadone treatment has been criticized for failing to encourage patients to eventually obtain a drug-free status after positive changes have been made in a patient's life. Many states require continued methadone maintenance justifications after certain periods of time (i.e. TN requires a justification every six months). Resources to pay for treatment may disappear in certain jurisdictions after an individual has been in treatment for a certain length of time. Option 2 fails to provide services to patients so they will effect positive changes and fails to challenge a patient to end his/her opiate dependency. Once again, Option 2 cannot be regarded as improving patient care nor can it be assumed to help methadone treatment find mainstream acceptance within the medical community.

The most damaging ramification of Option 2 will be a significant increase in the diversion of methadone followed by a concomitant increase in negative publicity and stigma associated with methadone treatment. Well meaning providers do not have the

ability to adequately assess whether or not patients are diverting the medication they receive. Patients may seek treatment in an adjoining state which allows more liberal take-home privileges than their home state allows. Patients who relapse will have several weeks worth of methadone doses which they can sell for heroin. Two days prior to their scheduled treatment date, these patients can stop using heroin, test negative for illicit drugs, and then receive another 3 1 days of marketable methadone doses. There also exists a significant increase in the possibility of patient overdoses due to methadone ingestion when an opiate dependent patient is given custody of 31 methadone doses. The DEA has stated,

"To relax controls in clearly identified areas which contribute to illicit trafficking would not enhance treatment, but instead would further erode public confidence in treatment and expand traffic and abuse of methadone."

The accreditation process surveys a previously accredited provider only once every three years. Given this survey schedule, accrediting agencies cannot adequately monitor inappropriate actions or abuses by providers regarding the granting of take-home medication. Thus, it is imperative that the regulations regarding the unsupervised use of methadone provide an inherent accountability among providers.

For the reasons mentioned above, it is not within the best interests of patients or treatment providers to support Option 2. A better solution would be to choose either Option 1 (retain existing system) or Option 4 (retain existing requirements subject to continuous review by accreditation bodies). Where special circumstances warrant more liberal take-home medication policies for individual patients, an alternative exceptions process may be developed with accrediting or state agencies to meet unusual patient needs. This approach would achieve the positive intent mentioned in the introductory materials without a degradation in the quality of treatment or an increase in the diversion of methadone and other associated negative ramifications.

Sincerely,

Janice M. Young-Conerly, Clinic Coordinator
DRD New Orleans Medical Clinic